Listing of the Claims

1. (Previously Presented) A method for identifying a patient having an increased risk for developing breast precancer or breast cancer, said method comprising the following steps:

(a) introducing a ductal access tool into a breast duct, said access tool comprising an elongated lumen;

(b) introducing a fluid into the breast duct through said elongated lumen;

(c) retrieving a ductal fluid sample from within the breast duct through said lumen, said ductal fluid being free of any ductal fluid from another duct of the breast; and

(d) detecting a viral agent in the ductal fluid sample.

2. (Original) A method as in claim 1, wherein the viral agent is selected from the group consisting of a whole virus, a portion of a virus, a viral protein, a viral nucleic acid, and a viral marker, in the sample.

3. (Cancelled) A method as in claim 1, wherein the ductal fluid is retrieved by nipple aspiration.

4. (Cancelled) A method as in claim 1, wherein the ductal fluid is retrieved by placing a ductal access tool in the duct and infusing fluid into the duct through the tool and retrieving from the accessed duct through the tool a portion of the infused fluid mixed with ductal fluid.

5. (Cancelled) A method as in claim 3, wherein steps (a)–(c) of the method are repeated for at least one additional breast duct.

6. (Previously Presented) A method as in claim 1, wherein, steps (a)–(d) of the method are repeated for a plurality of breast ducts.

7. (Original) A method as in claim 1, further comprising analyzing the ductal fluid for abnormal cytology.

8. (Previously Presented) A method as in claim 1, wherein a viral agent is detected, and further comprising the steps of: periodically repeating steps (a)-(c); and monitoring a variable selected from the group consisting of a viral titer, concentration of a viral agent, and presence of a viral marker in the ductal fluid samples.

9. (Previously Presented) A method as in claim 8, wherein the viral agent is monitored and the viral agent is selected from the group consisting of a whole virus, a portion of a virus, a viral protein, a viral nucleic acid, and a viral marker by taking repeated periodic ductal fluid samplings.

10. (Original) A method as in claim 8, wherein the periodicity is selected from the group consisting of daily, weekly, biweekly, monthly, bimonthly, every six months, annually, and biannually.

11. (Original) A method as in claim 1, wherein the viral agent is selected from the group consisting of papilloma virus, Epstein-barr virus, and herpes virus.

12. (Previously Presented) A method of treating a patient at risk for or having a breast precancer or breast cancer, said method comprising the following steps:

(a) introducing a ductal access tool into a breast duct, said access tool comprising elongated lumen;

(b) introducing a fluid into the breast duct through said elongated lumen;

(c) retrieving a ductal fluid sample from within the breast duct through said lumen;

(d) detecting a viral agent in the retrieved ductal fluid sample from the breast duct; and

(e) delivering to the patient a composition comprising an antiviral agent specific for the detected viral agent.

13. (Original) A method as in claim 12, wherein the viral agent is selected from the group consisting of a whole virus, a portion of a virus, a viral protein, a viral nucleic acid, and a viral marker.

14. (Previously Presented) A method as in claim 12, wherein the antiviral agent is delivered intraductally to the breast duct in which the viral agent has been detected.

15. (Previously Presented) A method as in claim 12, further comprising repeating steps (a)-(c) for a plurality of additional breast ducts; and wherein a viral agent is detected in at least one of the fluid samples separately retrieved from the plurality of additional breast ducts.

16. (Cancelled) A method as in claim 12, wherein viral agent is detected in a fluid sample collected from a plurality of breast ducts.

17. (Original) A method as in claim 12, wherein the viral agent is selected from the group consisting of papilloma virus, Epstein-barr virus, and herpes virus.

18. (Original) A method as in claim 12, wherein the antiviral agent is selected from the group consisting of an anti-HPV viral agent, and anti-EBV viral agent, and an anti-herpes viral agent.

19. (Previously Presented) A method as in claim 12, wherein said delivering step includes delivering the composition comprising said antiviral agent systemically.

20. (Previously Presented) A method as in claim 14, wherein analyzing comprises measuring a quality of the ductal fluid or ductal cells *in situ*.

Status of the Claims

Claim 5 has been cancelled. Claims 1, 2, 6-15, and 17-20 remain pending. Claims 3, 4, 16, and 21-22 were previously cancelled in response to a Restriction Requirement.

Objection to the Claims

Claim 5 was objected to due to being dependent on a cancelled claim. Claim 5 has been cancelled to expedite prosecution; therefore Applicant respectfully requests that the Examiner withdraw the objection.

The Rejections Under 35 U.S.C. §103(a) Should be Withdrawn

Claims 1, 2, 5-15, 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Love et al. (USP 6,221,622) and Makita et al. (Breast Cancer Research, 1991), in view of Sukumar et al. (USP 5,763,415), King et al. (JNCI, 1983), Noguchi et al. (American Journal of Pathology, 1994), Gross G. (Intervirology, 1997), and Androphy (Ciba Found, Symposium, 1986). The Applicant traverses this rejection.

First, the rejection of claims 1, 2, 5-15, 17-20 under 35 U.S.C. 103(a) as being unpatentable over Love et al. (USP 6,221,622) and Makita et al. (Breast Cancer Research, 1991), in view of Sukumar et al. (USP 5,763,415), King et al. (JNCI, 1983), Noguchi et al. (American Journal of Pathology, 1994), Gross G. (Intervirology, 1997), and Androphy (Ciba Found, Symposium, 1986) was addressed previously in Applicant's amendment filed March 9, 2004. The rejection under 35 U.S.C. 103(a) was withdrawn by the examiner in view of the Applicant's amendments to the claims. The Applicant respectfully argues that the rejection has already been successfully overcome by the previous amendment and that the claims should be allowed.

Secondly, even if the examiner maintains the rejection of claims 1, 2, 5-15, 17-20 under 35 U.S.C. 103(a), the Applicant disagrees that the present invention is unpatentable over Love et al. and Makita et al., in view of Sukumar et al., King et al., Noguchi et al., Gross G., and Androphy.

The examiner states that the present claims containing the claim limitation "comprising an elongated lumen" does not "...narrow the claim [to] a single lumen catheter." Applicant respectfully disagrees. Claims 1 and 12 are specifically drawn to methods of either identifying or treating a patient having an increased risk for developing breast precancer or breast cancer comprising multiple steps, one of which includes introducing a ductal access tool into a breast duct. Both claims contain the further limitation that the ductal access tool comprises an elongated lumen. The examiner states that the transitional term "comprising" does not exclude additional lumens. The Applicant respectfully disagrees. As stated in the MPEP 211.03, "Comprising" is a term of art used in claim language which means that the named elements are essential, but **other** elements may be added and still form a construct within the scope of the claim; *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts") (emphasis added). In the present case, the essential element of a ductal access tool comprising "an elongated lumen" has been presented by the Applicant in the singular form and has been previously argued as such. Thus the term "comprising" is used only to modify those other elements which may be found as part of a ductal access tool having a single lumen catheter.

The examiner also states that "[t]he Love et al reference still applies even if the claims were limited to a single lumen catheter because the reference teaches the use of a syringe to wash the breast duct." The Applicant respectfully disagrees. Love et al only mentions the use of a syringe to wash a breast duct through the lumen of a dual-lumen catheter. Nowhere in Love et al. is there a description of a single lumen catheter being used as the primary device to irrigate and remove fluid from a single breast duct.

Thus, Love et al fails to teach a method for identifying or treating a patient having an increased risk for developing breast precancer or breast cancer by introducing a ductal access tool into a breast duct when said access tool comprises a single elongated lumen. The deficiency of Love et al cannot be made up by Makita et al., Sukumar et al., King et al., Noguchi et al., Gross G., or Androphy. There is no teaching in any of the cited references of the use of a single lumen catheter to wash and collect fluid from a single breast duct. For all of the above discussed reasons, the Patent to Love et al. does not disclose the recited device. Additionally, it would not have been obvious to one of ordinary skill in the art to modify the dual lumen catheter of Love et al. so that it irrigate and retrieve a ductal sample because no motivation exists for such a modification and such a modification is contrary to the common knowledge of the ordinary artisan. Withdrawal of the rejection is requested.

Lastly, even assuming *arguendo* that the prior art establishes that it was known to use a single lumen catheter to irrigate and remove fluid from a single breast duct, King et al does not establish that papillomavirus can be detected in fluid samples obtained from breast ducts. The examiner states that King et al. "...teaches that fluid obtained from nipple aspirate can be used to assess the presence of a viral agent, papilloma and papilomatosis (see table 5)." The Applicant respectfully disagrees. Table 5 of King et al describes histologic types of breast disease tissues,

not breast fluid (see page 2, column 1, lines 3-10). King et al. describes the collection of NAF and the subsequent examination and classification of epithelial cells contained in the NAF (see page 1, column 1, lines 31-36). There is no description in King et al. of the detection of a viral agent in ductal fluid. The histological types described in table 5 come from tissues subsequently collected from biopsies or mastectomies, not from the washing of the breast ducts. Thus, King et al fails to teach a method for identifying or treating a patient having an increased risk for developing breast precancer or breast cancer by introducing a ductal access tool into a breast duct when said access tool comprises a single elongated lumen, introducing a fluid into the breast duct through said elongated lumen; retrieving a ductal fluid sample from within the breast duct through said lumen, said ductal fluid being free of any ductal fluid from another duct of the breast; and detecting a viral agent in the ductal fluid sample. There is no teaching in any of the other cited references of detecting a viral agent in the ductal fluid sample.

For all of the above-discussed reasons, Applicant submits that all grounds of rejection under 35 U.S.C. §103(a) have been overcome. Withdrawal of the rejection is requested. Applicant respectfully submits that claims 1, 2, 6-15, and 17-20 are allowable and that the application is now in condition for allowance.

If any questions or issues remain, the resolution of which the Examiner feels would be advanced by a conference with Applicant's attorney, the Examiner is invited to contact Applicant's attorney at the number noted below.

Conclusion

In light of the arguments presented above, Applicants respectfully submit that the claims are in condition for allowance. Early notice to this effect is solicited.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 502855 referencing attorney docket number 12.001911.

Respectfully submitted,

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